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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/645,764

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Pu Zhou

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CROMPTON, SEAGER & TUFTE, LLC
1221 NICOLLET AVENUE
SUITE 800
MINNEAPOLIS, MN 55403-2420

EXAMINER

KOHARSKI, CHRISTOPHER

ART UNIT

PAPER NUMBER

3763

MAIL DATE

DELIVERY MODE

02/21/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/645,764	Applicant(s) ZHOU, PU	
	Examiner CHRISTOPHER D. KOHARSKI	Art Unit 3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 November 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 10, 12 and 26-33 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 10, 12 and 26-33 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 8/20/2003 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 11/27/2007 has been entered.

Response to Amendment

Claim Rejections - 35 USC § 112

Claim 26, 27, 28 and 31 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Examiner asserts that the specification lacks support for a "step-wise transition" between the wire diameters.

Drawings

The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the stepwise transition from the distal diameter to the proximal diameter must be shown or the feature(s) canceled from the claim(s). Figures 5-6, do not show any transition between the wire diameters. No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

Art Unit: 3763

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 10, 12, and 26-33 are rejected under 35 U.S.C 103(a) as being unpatentable over Schoenholtz (USPN6,203,534) in view of Cohen (USPN5,330,521) (or Klint (US2002/0074501)).

Regarding claims 10, 12, and 26-33, Schoenholtz discloses a catheter (12) with a braided reinforcing layer (24) that is made from two or more continuous wires woven together made up of stainless steel (col 4, ln 10-35) (Figures 1-3) with a protective overcoat (42, 22) over this woven wire reinforcement. Schoenholtz meets the claim limitations as described above except for the distal and proximal braided section having a decreasing cross sectional area.

However, Cohen teaches an electrical lead including a wire core having a cross-sectional area, which differs over its length.

Regarding claims 10, 12, and 26-33, Cohen teaches (Figure 4) an implantable tubular device that uses a wire-reinforcement coil (42) with a diameter that decreases an incremental step-wise along its length (dL, dS) along with various production methods (Figure 4, col 8, ln 60-70, col 9, ln 1-43).

At the time of the invention, it would have been obvious to add the reinforcement member teachings of Klint to the system of Schoenholtz because as taught in Klint the reduction of the core diameter of the reinforcement member allows for larger transverse flexibility and higher tip softness without comprising torque stability. The references are

analogous in the art and with the instant invention; therefore, a combination is proper.

Therefore, one skilled in the art would have combined the teachings in the references in light of the disclosure of Cohen (cols 1-2).

Additionally, Klint teaches a guidewire with lengthwise diameter variability.

Regarding claims 10, 12, and 26-33, Klint teaches (Figure 2) a tubular device that consists of a wire-reinforcement coil (7,8,9) comprising 2-8 helical wound wires with a diameter that decreases in an incremental step-wise along its length (15, 13, 11).

At the time of the invention, it would have been obvious to add the reinforcement member teachings of Cohen to the system of Schoenholtz because as taught in Cohen the reduction of the core diameter of the reinforcement member allows for tip flexibility and tracking within a patient without overly compromising the tip strength. The references are analogous in the art and with the instant invention; therefore, a combination is proper. Therefore, one skilled in the art would have combined the teachings in the references in light of the disclosure of Klint ([0001-0022]).

The modified Schoenholtz meets the claim limitations as described above except for the specific 1.5 mm to 1.0 mm diameter sizes.

Regarding claims 10, 12, and 26-33, it would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the braid diameters as claimed by Applicant since Cohen that other varied diameters depending on the particular application may be employed (col 9, ln 10-25) and Klint discloses several varied diameters depending on the application of the medical device, and since

it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. *In re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA 1980).

Response to Arguments

Applicant's arguments filed 11/27/2008 have been fully considered but they are not persuasive. Applicant's Representative asserts that the combination of the Schoenholtz and Cohen reference do not teach the change in diameter in a step-wise transition or a change in diameter from 1.5 mm to 1.0 mm from the distal to proximal wire cross sections

Examiner has fully considered applicant's arguments but they are not persuasive. It is examiners position that given a careful reading, the claims do not distinguish over the prior art of record.

Examiner asserts that the definition of a "step-wise" transition is not described or depicted in Applicant's disclosure, thus the broadest reasonable definition is applied. Examiner considers the changes in the diameters of each of the references (Cohen, Klint) as an incremental step-wise change and thus meets the claim limitations. Regarding the Cohen reference, Examiner asserts that Cohen teaches a base diameter difference of 0.2 mm to 0.1 mm but clearly discloses other may be employed depending on the application (col 9, 10-25). Additionally, Cohen teaches (col 8, ln 40-60) that the decreasing cross sectional area effects the electrical resistance so thus the length of the decreased diameter section is minimized (not the diameter), if anything, increasing the effective diameter will minimize the discussed electrical conductance issues.

The prior art of record teaches all elements as claimed and these elements satisfy all structural, functional, operational, and spatial limitations currently in the claims. Therefore the standing rejections are proper and maintained.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher D. Koharski whose telephone number is 571-272-7230. The examiner can normally be reached on 5:30am to 2:00pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nick Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Date: 2/06/2008

/Christopher D Koharski/
Examiner, Art Unit 3763

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/Nicholas D Lucchesi/
Supervisory Patent Examiner, Art Unit 3763